MAR 2 5 2002

15.0 Premarket Notification Summary K004009

General Information

Device Name

Common or Usual Name:	Biological Indicator Reader/Incubator
Proprietary Name:	3M™ Attest™ 290 Auto-reader
Classification Name:	This device is an accessory to Biological Sterilization Process Indicators (21CFR§880.2800).

Establishment Registration Number

The establishment registration number for 3M Company is 2110898.

The 3M™ Attest™ 290 Auto-reader is manufactured and packaged at the following facility:

3M Company
1617 North Front Street
New Ulm, MN 56073

Phone: 651-733-7605
Fax: 651-737-5320
Establishment Number 2183581

Device Classification

Class:	Class II
Classification Panel:	General Hospital (80)
Product Code:	Accessory to FRC

Performance Standards

The Food and Drug Administration has not developed performance standards under Section 514 for the 3M™ Attest™ 290 Auto-reader.

Nonetheless, development of the 3M™ Attest™ 290 Auto-reader was conducted in compliance with the following standards and guidelines, as appropriate:

- ISO 90001-1994 and EN 46001-1997 Section 4.4 "Design Control"
- 21CFR§820.30 "Design Controls"

- Standard for Electrical Equipment for Laboratory Use. UL 3101, Part 1, General Requirements, First Edition 1993.

- Canadian standard for the Safety Requirements of Electrical Equipment for Measurement Control and Laboratory Use. CAN/CSA C22.2, No. 1010.1-92, Part 1. General Requirements. 1992.

Indication for Use

The 3M Model 290 Attest Auto-reader is designed to incubate and automatically read the 3M Attest 1291 and/or 3M Attest 1292 Rapid Readout Biological Indicators at 60° C, for a final negative fluorescent reading at 1 hour for 1291or 3 hours for 1292.

The 3M Model 290 Attest Auto-reader is also designed to allow for further incubation of the Attest 1291 and/or the Attest 1292 Rapid Readout Biological Indicators for a final negative, visual pH color change of the growth media at 24 hours for 1291 and 48 hours for 1292.

A positive fluorescent reading or a visual pH color change indicates a steam sterilization process failure.

Device Description

The 3M attest 290 Auto-reader is an accessory to the 3M attest series of Rapid Readout Biological Indicators (BI) that are incubated at 60° C. The initial BIs in this series to receive market clearance were the 1291 (K900771) and 1292 (K926364). The purpose of these BIs is to assess whether a potential failure of a steam sterilization cycle has occurred. Both of these initial Premarket notifications listed the 3M Attest 190 Auto-reader as an accessory. Since the Model 190 was cleared as part of these submissions, it serves as the predicate device for the new Model 290.

The Model 290, like its predecessor, serves only two purposes. First, it serves as an incubator for the time period required to obtain either a rapid (i.e., fluorescent) readout or to observe a colorimetric change, second, the device determines whether a potential sterilization cycle failure may have occurred by measuring the intensity of fluorescence of the medium inside the BE. The components and operational characteristics used to accomplish these two tasks are described in the following paragraphs.

Operationally, the device functions as follows. Activation of the unit is accomplished by plugging the device's power cord into a standard 115 volt wall receptacle. A series of internal self-tests will automatically be performed by the Model 290 to verify operational status. During the initial war-up period, the digital display panel will show a "C1" caution code indication that the device has not reached operational temperature. Similarly, if the incubation temperature should either go below or above the acceptable range of 58 °C to 62 ° C, then an "E1" error code will be displayed and the device will cease functioning. When any of the error conditions such as this occurs, the Operating Instructions recommend that the unit's power be cycled so that initial self-test routines can again be performed. If the error condition returns, the device is to be sent to 3M for service.

Incubation is performed by lifting the cover, crushing the glass ampoules of the BIs in the "crusher well", tapping the BIs to ensure that the media wets the strip, and placing BIs into any of the twelve (12) wells provided in the "incubator block".

Let us return to the second function of the Model 290. That is, obtaining a rapid readout based upon the fluorescence of the BI's media. The measurement of fluorescence is initiated by placement of a BI into any of the incubation wells. The reader/incubator wells are color coded to match the color of the top of the BIs. The incubator block may be color coded as all blue (for use with 1291 BIs only), all brown (1292 BIs only), or half blue and half brown. When a BI is initially placed into a well, the Model 290 will detect its presence. A yellow light on the front panel will light indication that incubation has begun. A read sequence in initiated. A subsequent "positive" reading is interpreted as an indication of a potential sterilization cycle failure. The positive finding is indicated to the user by a red "+" light on the front panel as well as an audible alarm. The alarm may be muted by the operator when a positive result is obtained. Pressing the mute button disables the alarm only for that specific BI which was just identified as positive. Should another BI become "positive", the alarm will again sound. Negative results are identified by a green "-" light on the front panel.

The Model 290 software will warn the operator if various process errors occur which could result in an erroneous result. For example,

- If an operator mistakenly removes a BI from its well while it is in the process of incubation, a "C2" caution code will be displayed, all indicator lights (yellow •, red +, and green -) will flash, and an audible alarm will sound. The user has ten (10) seconds to return the BI to its well.

- The Model 290 software verifies that the proper incubation will is being read. Should erroneous reading be obtained, an "E9" error code will be presented on the display panel.

- If the bulb intensity is below a minimum acceptable level, then an "E8" error code is displayed on the digital display.

The primary difference between the Model 290 and the Model 190 (predicate device) is that the former is software controlled; whereas, the latter is manually operated. According to Figure 2 of FDA's reviewer's guidance document, use of software in this type of medical device may pose a "Minor Level of Concern". This is due to the fact that the software does not: (1) control a life supporting device, (2) control deliver of harmful energy, (3) control treatment deliver, (4) provide diagnostic information, nor (5) perform vital signs monitoring. The Model 290 software was written by 3M. Software verification test plans were developed to assess whether the device operated per design intent. Separate plans were drafted for those functions considered "critical" to the proper measurement of BI fluorescence as well as those deemed "non-critical" (i.e., all other operations).

Similarly, functional and hardware tests have been performed to verify that the Model 290 operates per design intent and within the specifications documented in the Device Master Record (DMR).

Substantial Equivalence K004009

The 3M Attest 290 auto-reader is substantially equivalent to the 3M Attest 190 Auto-reader (predicate device). The Model 290 and Model 190 have the same intended use and similar features which include: incubation of biological indicators at 60°C ± 2°C, use of a UV lamp to measure fluorescence of the BI medium, and colored indicator lights to indicate positive or negative results. The Model 290 is being introduced with software operation to replace the Model 190 that required most of the functions to be performed manually by the device operator (e.g., timing of BI incubation duration and placing the BI in proximity to the fluorescent lamp). Replacing manual operation of an auto-reader with software control does not alter the basic function of the device nor change the types of safety and effectiveness issues associated with its use. 3M Company concludes that the Model 290 and the predicate Model 190 are substantially equivalent.

Cynthia Lamarucciola 18 March 2002

Cynthia Lamarucciola
Senior Regulatory Affairs Associate
3M Medical Division

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 5 2002

Mr. Stephen Norsted
3M Corporation
5353 Wayzata Boulevard, Suite 505
Minneapolis, Minnesota 54416

Re: K004009
Trade/Device Name: 3M Attest 290 Auto-Reader
Regulation Number: 880.2800
Regulation Name: Biological Indicator Reader
Regulatory Class: II
Product Code: FRC
Dated: January 25, 2002
Received: January 28, 2002

Dear Mr. Norsted:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K004009/S3

11.0 Indication for Use

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A positive fluorescent reading or a visual pH color change indicates a steam sterilization process failure.

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K004009